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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,610	02/26/2004	Jingrong Jean Cui	034536-1148	2828

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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,610	CUI ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 29,1Sep04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-43, drawn to chemical compounds of formulae **1**, **2**, **3**, **4**, **5** and **6**, classified in class/subclasses 544/60, 120, 357, 405 and 408.

II. Claims 44-47, drawn to methods of treating abnormal cell growth in a mammal, comprising administering to the mammal a therapeutically acceptable amount of a chemical compound from Group I as set forth *supra*, including treating *all* manner of cancers, which methods are classified in class/subclasses 514/227.8, 235.8, 252.11, 255.05 and 255.06.

III. Claim 48, drawn to a method of treating abnormal cell growth in a mammal, comprising administering to the mammal a therapeutically acceptable amount of a chemical compound from Group I as set forth *supra*, wherein the method further comprises administering an anti-tumor agent selected from mitotic inhibitors, alkylating agents, anti-metabolites, intercalating antibiotics, growth factor inhibitors, cell cycle inhibitors, enzymes, topoisomerase inhibitors, biological response modifiers, antibodies, cytotoxics, anti-hormones, anti-androgens and mixtures thereof, classified in classes 514, in subclasses depending on the chemical identity of the therapeutic agents administered. Since all of the therapeutic agents administered in the practice of the method according to claim 48 are only functionally described (as opposed to being described chemically), the exact subclasses cannot be set forth.

The inventions are distinct, each from the other because:

Inventions I, II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compounds according to Group I are not limited in their utility to (allegedly) controlling abnormal cell growth. The compounds could be employed in *in vitro* kinase assays. Methods of treating cancers are known, and are practiced with materially different agents than are embraced by Group I of this Requirement. The multiple therapeutic agent method of claim 48 is (allegedly) useful for the treatment of some abnormal cell growths not treatable by the administration of Group I compounds alone.

Additionally, the search required for determination of the patentability of Group I will not include all of the search required for determination of the patentability of Groups II and III, because the methods as set forth in Groups II and III require a search of the state of the art, necessary for determining whether the first paragraph of 35 U.S.C. 112 has been satisfied. This additional search of the state of the art in treatments of abnormal cell growth disorders and cancers is not included in the search of the chemical literature for simple disclosures of compounds according to Group I.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This Requirement is further set forth as follows:

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to voluminous patentably distinct species of the claimed invention, such as those according to claims 36-43, each of which is independent. The generic claims in the application read on vast numbers of possible compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, *and a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The search pursuant to applicants' election of species will be conducted as explained in MPEP § 803.02, and will not be unnecessarily broadened.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This Requirement, finally, is subject to the following:

The examiner has required restriction between compounds and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined method of use claims will be withdrawn, and the rejoined method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Comments

It is requested that applicants' counsel, in making the election of the single disclosed species for examination purposes, indicate where in the lengthy Markush claims that species is found, should that species be recited in one of claims 36, 37, 38 or 39.

In claim 38, on page 305 of the application as originally filed, at line 21, the compound 7-[4-(3,5-dimethyl-piperazine-1-carbonyl)-phenyl]-2-phenyl-4H-pyrido[3,2-b][1,4]-oxazin-3-one is named. This compound does not follow any of formulae **1**, **2**, **3**, **4**, **5** and **6** in claims 1-35. Thus, at least one compound in the Markush claims represents a significantly different type of compound from most of those disclosed.

Claims 40-43 refer to tables. These claims would be rejected under the second paragraph of 35 U.S.C. 112, because those tables are not defined in the claims.

The methods in the application, in their present form are not likely to be found enabled for their full scope. Upon rejoinder, rejections under the first paragraph of 35 U.S.C. 112 will be necessary. Claim 44 is drawn to the treatment of all abnormal cell growths; it is not limited to treatment of cancers. Treatment of cancers, generally, is not enabled by the disclosure, at any rate.

Declaration

The declaration is objected to under 37 CFR 1.52(c), because non-initialed and/or non-dated alterations to it have been made, specifically, co-inventor Iriny Botrous' signature has been lined through.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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